UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DUSA PHARMACEUTICALS, INC.,

and

SIRIUS LABORATORIES, INC., a wholly-owned subsidiary of DUSA PHARMACEUTICALS, INC.,

Plaintiffs,

v.

RIVER'S EDGE PHARMACEUTICALS, LLC,

Defendants.

CIVIL ACTION NO.
06-1843 (SRC)

DEMAND FOR JURY TRIAL

VERIFIED COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF FOR PATENT INFRINGEMENT

Plaintiffs DUSA Pharmaceuticals, Inc. and Sirius Laboratories, Inc., a wholly-owned subsidiary of DUSA Pharmaceuticals, Inc., complain of defendant River's Edge Pharmaceuticals, LLC as follows:

JURISDICTION

1. This is an action for patent and copyright infringement arising under the Patent Laws of the United States, 35 U.S.C. §101, et seq. This Court has subject

matter jurisdiction over this patent infringement action under 28 U.S.C §§ 1331, 1332 and 1338(a).

2. Defendant regularly conducts business in New Jersey, and specifically in Mercer County, has offered to sell, offers to sell, has sold and/or sells infringing products in New Jersey and is subject to specific personal jurisdiction in New Jersey.

3. Based on information and belief, Defendant River's Edge Pharmaceuticals, LLC has sold and continues to sell a variety of products within New Jersey, and specifically within Mercer County, through its distributors to nationwide retailers including Walgreen Co. and Wal-Mart Stores, Inc. and its contacts with New Jersey are continuous and systematic making it subject to general personal jurisdiction in New Jersey.

4. Venue is therefore proper in this Court pursuant to 28 U.S.C. § 1391(b).

THE PARTIES

5. Plaintiff DUSA Pharmaceuticals, Inc. ("DUSA") is a publicly traded pharmaceutical company incorporated in the State of New Jersey, with principal offices at 25 Upton Drive, Wilmington, Massachusetts. DUSA's registered agent for service in New Jersey is Nanette W. Mantell of Reed Smith LLP located in Mercer County at 136 Main Street, Suite 250, Princeton Forrestal Village, Princeton, New Jersey 08540.

6. Plaintiff Sirius Laboratories, Inc. ("Sirius II") is a wholly-owned subsidiary of DUSA incorporated in the State of New Jersey with principal offices at 100 North Fairway Drive, Suite 130, Vernon Hills, Illinois. Sirius II's registered agent for service in New Jersey is Nanette W. Mantell of Reed Smith LLP located in Mercer County at 136 Main Street, Suite 250, Princeton Forrestal Village, Princeton, New Jersey 08540.

7. Based on information and belief, Defendant River's Edge Pharmaceuticals, LLC ("River's Edge") is a limited liability company organized and existing under the laws of the State of Georgia, with its principal place of business at 5400 Laurel Springs Parkway, Building 504, Suwanee, Georgia.

U.S. PATENT NO. 6,979,468

8. On December 27, 2005, U.S. Patent No. 6,979,468 ("the '468 Patent"), entitled "Oral Composition and Method for the Treatment of Inflammatory Cutaneous Disorders" was duly and validly issued to the inventor Frank Pollard. Exhibit A.

9. The '468 Patent was initially assigned to Sirius Laboratories, Inc., a privately held company incorporated in the State of Illinois, with principal offices at 100 Fairway Drive, Suite 130, Vernon Hills, Illinois ("Sirius I").

10. The '468 Patent was subsequently and is currently assigned to DUSA.

11. The '468 patent is directed to an oral pharmaceutical preparation for the treatment of inflammatory skin disorders comprising nicotinamide in an immediate release form and zinc in a sustained release form.

12. On or about March 10, 2006, DUSA acquired Sirius I by merger, thus dissolving Sirius I and establishing a DUSA wholly-owned subsidiary named Sirius Laboratories, Inc. ("Sirius II").

13. At all times prior to and since issuance, Sirius I, Sirius II, and/or DUSA Pharmaceuticals, Inc. has marked its applicable products including its reformulated Nicomide® product containing immediate release nicotinamide and sustained release zinc, and advertising with "Patent Pending" or the '468 Patent number, providing constructive notice to the public and the defendant.

PRIOR COMMUNICATIONS BETWEEN THE PARTIES

14. On or about March 17, 2006, Plaintiffs received a letter from Steven J. Hultquist of Intellectual Property Technology Law on behalf of an anonymous client identifying prior art that Mr. Hultquist claimed rendered the '468 patent invalid and requesting that Plaintiffs file a dedication to the public and disclaimer of the remaining term of the '468 patent. Exhibit B.

15. On or about March 23, 2006, Plaintiffs, through counsel, responded to Mr. Hultquist's letter and invited Mr. Hultquist's client to enter into discussions

regarding the unidentified client's "activities or intended activities, and a potential business resolution." Exhibit C.

16. On or about March 28, 2006, Defendant River's Edge, absent any threat or apprehension of litigation from Plaintiffs, filed a lawsuit against DUSA and Sirius II in the United States District Court for the Northern District of Georgia, Gainesville Division styled 2:06-CV-0045-WCO (the "Georgia Complaint") including claims of promissory estoppel, fraud, and seeking declaratory judgment of patent invalidity and attaching the correspondence between Mr. Hultquist and Plaintiffs' counsel. Exhibit D.

17. Because neither DUSA nor Sirius II ever threatened River's Edge or created a reasonable apprehension of litigation for patent infringement against River's Edge, they will seek to dismiss the declaratory judgment action in Georgia.

18. In the Georgia Complaint, River's Edge admitted that it began marketing its infringing NIC 750 product on or about March 27, 2006.

19. Days later, NIC 750 appeared in the National Drug Data File® ("NDDF") maintained by First DataBank, Inc., a resource regularly consulted by physicians, pharmacists, hospitals, and clinicians to identify potential substitute equivalents of branded pharmaceuticals, and, upon information and belief, River's Edge has listed its NIC 750 product in such a way that users of the NDDF will identify NIC 750 as an equivalent substitute for DUSA's patented, prescription Nicomide® product.

20. Upon information and belief, River's Edge is currently marketing its NIC 750 product as a substitution drug in direct competition against Plaintiffs patented Nicomide® product.

21. Counsel for DUSA, Adam Floyd, first left a voicemail message for Joshua Tropper, counsel for River's Edge, on March 30, 2006 requesting a sample of the NIC 750 product.

22. Mr. Floyd followed that voicemail with a letter on March 31, 2006 asking Mr. Tropper for a sample and all product packaging for the NIC 750 product.

23. Mssrs. Brazier and Tropper finally responded to Mr. Floyd by telephone on April 4, 2006 indicating that they would try to provide DUSA with a sample of NIC 750 early in the week of April 10, 2006. Mr. Floyd confirmed that agreement in another letter on April 4, 2006.

24. Upon learning that NIC 750 had been listed in the NDDF, Mr. Floyd again wrote to Mr. Tropper on April 6, 2006 requesting (1) a copy of the submission made by River's Edge to First DataBank, (2) authorization for Mr. Floyd to obtain that information from First DataBank directly, or (3) a stipulation from River's Edge that NIC 750 infringes one or more claims of the '468 patent and a consent to enter into a preliminary injunction until the parties could resolve their issues.

25. Despite requesting a response from Mr. Tropper by 12:00 pm CST on April 7, 2006, Mr. Floyd did not again hear from River's Edge's counsel until April 10,

2006, by letter from Mr. Robert Brazier. In that letter, Mr. Brazier refused to stipulate to infringement relying solely on River's Edge's assertions in the Georgia Complaint that the '468 patent is invalid, and demanded that Mr. Floyd identify the patent claims DUSA believes are infringed by NIC 750. Mr. Brazier did not respond at all to Mr. Floyd's requests concerning River's Edge's First DataBank submission.

26. Michael Smith, also counsel for DUSA, responded by letter on April 11, 2006 asking River's Edge to stipulate that all limitations of at least Claim 1 of the '468 patent were met assuming the '468 patent is valid and reiterating DUSA's request that River's Edge agree to a preliminary injunction.

27. Mr. Smith followed up with a telephone call to Mssrs. Brazier and Tropper on April 13, 2006 once again reiterating DUSA's request for a product sample and/or a stipulation of infringement of the '468 patent.

28. On April 17, 2006, Mr. Smith received a sample of the NIC 750 product from Mr. Brazier in its original packaging showing NDC No. 68032-132-60 from Lot No. 603022.

29. As of this date, River's Edge refuses to stipulate to infringement or even agree that NIC 750 must read on every limitation of claim 1 of the '468 patent, despite the clear admissions made by River's Edge in its own NIC 750 product insert.

30. River's Edge's refusal to consent to a preliminary injunction has forced DUSA to file, concurrently with this Verified Complaint, an Emergency Motion for a Temporary Restraining Order seeking immediate relief from this Court to protect its patent rights and maintain the *status quo* between the parties while the issues of this case are being resolved.

FIRST CLAIM FOR RELIEF: PATENT INFRINGEMENT

31. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-30.

32. Upon information and belief, Defendant River's Edge has imported, made, used, sold, and/or offered to sell a prescription pharmaceutical product called "NIC 750" embodying the claimed inventions of the '468 Patent within the United States. NIC 750 infringes at least one or more claims of the '468 Patent. River's Edge began marketing and offering to sell NIC 750 at least as early as March 27, 2006.

33. Based on the NIC 750 product package insert, NIC 750 contains 750 mg. of nicotinamide, 25 mg. of zinc oxide, 1.5 mg of cupric oxide and 500 mcg of folic acid formulated for biphasic delivery such that "[t]he biphasic delivery system facilitates the immediate release of 750 mg Nicotinamide, 1.5 mg Cupric Oxide, and 500 mcg Folic Acid, as well as, the sustained release of 25 mg Zinc Oxide." See Exh. C. of the Brief in Support of Plaintiffs' Emergency Motion for a

Temporary Restraining Order. A full claim chart detailing the literal infringement of claims 1-15 of the '468 patent is attached to the Brief as Exh. B.

34. Upon information and belief, Defendant River's Edge has induced and is actively inducing others to directly infringe at least one or more claims of the '468 Patent. Specifically, Defendant River's Edge actively encourages others to sell, offer to sell, and/or use NIC 750 embodying the claimed inventions of the '468 Patent within the United States through its distributors to nationwide retailers including Walgreen Co. and Wal-Mart Stores, Inc. NIC 750 is also being offered for sale through online distributor drugstore.com which has a primary distribution center located in New Jersey. Defendant River's Edge has intentionally done so having knowledge of the '468 Patent and therefore knew, or should have known, that it actively had induced others to commit acts that constitute direct infringement of the asserted claims of the '468 Patent.

35. Upon information and belief, Defendant River's Edge's infringing conduct is unlawful and willful and will continue unless enjoined by this Court.

36. Defendant River's Edge's infringement of one or more claims of the '468 Patent has caused and will continue to cause irreparable injury to Plaintiffs for which there is no adequate remedy at law.

37. Plaintiffs have suffered damages as a result of Defendant River's Edge's infringement of one or more claims of the '468 Patent and will continue to suffer damages as a result of Defendant River's Edge's continued infringement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment:

(a) that Defendant River's Edge has infringed one or more claims of the '468 Patent;

(b) that a temporary restraining order, and a preliminary and permanent injunction be issued against further infringement of the claims of the '468 Patent by Defendant River's Edge, and their officers, agents, servants, employees, attorneys and all those persons in active concern or participation with Defendant;

(c) that Defendant River's Edge be ordered to account for each infringement of the claims of the '468 Patent occurring since December 27, 2005 in an amount adequate to compensate Plaintiffs for each such infringement;

(d) that Defendant River's Edge be ordered to pay Plaintiffs' costs, expenses and prejudgment interest as provided for by 35 U.S.C. § 284;

(e) that this case is exceptional within the meaning of 35 U.S.C. § 285 and award Plaintiffs their reasonable attorney fees;

(f) that the Court determine that Defendant River's Edge willfully infringed one or more claims of the '468 Patent and enhance damages up to treble as provided by 35 U.S.C. § 284; and

(g) that Plaintiffs be granted such other relief as the court deems just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a jury trial on all issues triable of right by a jury.

Respectfully submitted,

Date: April 20, 2006

DANIEL MATEO
REED SMITH LLP
136 Main Street, Suite 250
Princeton Forrestal Village
Princeton, NJ 08540
Tel: (609) 987-0050
Fax: (609) 951-0824

TRACY ZURZOLO FRISCH
REED SMITH LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103
Tel: (215) 851-8100
Fax: (215) 851-1420

Of Counsel:
ADAM V. FLOYD
TRACEY B. DAVIES
MICHAEL J. SMITH
CHRISTOPHER V. POPOV
REESE P. MCKNIGHT
VINSON & ELKINS L.L.P.
The Terrace 7
2801 Via Fortuna, Suite 100
Austin, Texas 78746-7568
Tel: (512) 542-8400
Fax: (512) 542-8612
Attorneys for Plaintiffs DUSA Pharmaceuticals, Inc. and Sirius Laboratories, Inc.

CERTIFICATION PURSUANT TO L.Civ.R. 11.2

I certify that to the best of my knowledge, information and belief the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, except that Defendant River's Edge Pharmaceuticals, LLC improvidently filed a declaratory judgment action against Plaintiffs in the United States District Court, Northern District of Georgia, Gainsville Division, Case No. 2:06-CV-0045-WCO.

Tracy Zurzolo Frisch

Dated: April 20, 2006

PRCLIB-381498.14/20/06 2:37 PM

Exhibit A

US006979468B1

(12) **United States Patent**
Pollard

(10) **Patent No.: US 6,979,468 B1**
(45) **Date of Patent: Dec. 27, 2005**

(54) **ORAL COMPOSITION AND METHOD FOR THE TREATMENT OF INFLAMMATORY CUTANEOUS DISORDERS**

(75) Inventor: **Frank Pollard**, Long Grove, IL (US)

(73) Assignee: **Sirius Laboratories**, Vernon Hills, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 58 days.

(21) Appl. No.: **10/313,165**

(22) Filed: **Dec. 6, 2002**

(51) **Int. Cl.**[7] **A61K 31/455**; A61K 31/315; A61K 33/30; A61K 33/34; A61P 17/10

(52) **U.S. Cl.** **424/643**; 424/400; 424/458; 424/468; 424/630; 424/635; 424/637; 424/638; 424/641; 424/643; 514/46; 514/47; 514/249; 514/355; 514/499; 514/859; 514/861; 514/863; 514/864; 514/865; 514/886; 514/887; 514/964

(58) **Field of Search** 514/46, 47, 355, 514/859, 861, 863–865, 886–887, 964, 249, 514/499; 424/400, 458, 468, 641, 643, 630, 424/635, 637, 638

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,505,896	A	3/1985	Bernstein	
4,725,609	A	2/1988	Kull et al.	
5,459,153	A	10/1995	Leung	
5,571,441	A *	11/1996	Andon et al.	252/1
5,759,559	A	6/1998	Fitzjarrell	
5,866,106	A	2/1999	Papay	
5,972,382	A	10/1999	Majeed et al.	
5,972,985	A	10/1999	Thomas et al.	
5,972,999	A	10/1999	Murad	
5,989,523	A	11/1999	Fitzjarrell	
6,020,351	A	2/2000	Pero	
6,133,317	A	10/2000	Hart	
6,177,476	B1 *	1/2001	Peterson et al.	514/722
6,248,763	B1	6/2001	Scivoletto	
6,299,886	B1	10/2001	Piper	
6,361,800	B1	3/2002	Cooper et al.	
6,403,349	B1	6/2002	Mukerji et al.	
6,407,141	B1	6/2002	Hart	
6,660,293	B2 *	12/2003	Giordano et al.	424/439
2003/0147930	A1 *	8/2003	Jun et al.	424/401

OTHER PUBLICATIONS

Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton (PA), 1985, pp. 1644-1654.*
Kirk-Othmer Encyclopedia of Chemical Technology, 4th rd., John Wiley & Sons, NY, 1993, pp. 274-300.*

* cited by examiner

Primary Examiner—John Pak
(74) *Attorney, Agent, or Firm*—Sandra B. Weiss; Jones Day

(57) **ABSTRACT**

A method and composition for the treatment of acne vulgaris, acne rosacea, and other inflammatory skin conditions comprises the oral administration of a composition comprising a dose of nicotinamide delivered at levels substantially in excess of normal dietary levels, the nicotinamide being delivered in combination with zinc. The composition may also include quantities of copper and folic acid. In a most preferred embodiment, the nicotinamide and copper each are present in immediate release formats, while the zinc is present in a sustained release format.

16 Claims, No Drawings

ORAL COMPOSITION AND METHOD FOR THE TREATMENT OF INFLAMMATORY CUTANEOUS DISORDERS

BACKGROUND OF THE INVENTION

This invention relates to the use of a unique oral preparation for the treatment of inflammatory skin conditions. More particularly, this invention relates to a composition and method for the treatment of inflammatory skin conditions such as acne rosacea and acne vulgaris comprising an immediate release form of nicotinamide in combination with a sustained release form of zinc combined complementary other active ingredients to provide optimum levels of several different treatment modalities. The combination of an immediate release nicotinamide and sustained release zinc provides an unexpected synergistic anti-inflammatory effect that is not observed with combinations of immediate release forms of both chemicals.

Acne vulgaris is an inflammatory disease of the pilosebaceous glands characterized by an eruption of the skin, often pustular in nature but not suppurative. Acne is a common affliction of the adolescent and affects a small but significant percentage of the adult population. Acne lesions are of four basic types: comedones (blackheads or whiteheads), papules, pustules, and cysts (or nodules). Various topical agents are utilized in the treatment of acne and these include sulfur, resorcinol, salicylic acid, benzoyl peroxide, vitamin A acid and topical antibiotics. Other treatment methods include topically applying various scrubbing or abrasive compositions, topically applying deep cleaning or astringent compositions, and also exposure to ultraviolet radiation. Acne involvement can result in unsightly lesions, particularly on the face, and in some cases in severe scarring.

Acne rosacea is another inflammatory skin affliction characterized by erythema with or without an acneiform component (papules, pustules, or nodules). Rosacea typically occurs in adults of about 30–50 years of age. The acneiform component or rosacea has been treated in the past in a fashion similar to the treatment for acne vulgaris. Systemic antibiotics have also been helpful.

Nicotinamide and nicotinic acid are water soluble vitamins whose physiologically active forms include nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Nicotinamide and nicotinic acid have been used routinely to treat pellegra for which they are therapeutic. Nicotinamide is available from a variety of pharmaceutical houses such as Roche Vitamin, Inc., of Nutley, N.J.; Armor Pharmaceutical Company located in Phoenix Ariz.; Brown Pharmaceutical Company Inc. located in Los Angeles, Calif.; and Keith Pharmaceutical Inc. located in Miami, Fla.

It is known that a high dose of immediate release nicotinamide will have greater bioavailability and greater extended activity than that of a sustained release application.

U.S. Pat. No. 4,505,896 teaches the use of oral compositions containing nicotinamide in the treatment of acne vulgaris. The nicotinamide is administered orally in doses of 100–600 milligrams per day in divided doses taken 2 to 4 times per day. The treatment was reported to decrease inflammatory lesions such as papules, pustules, and cysts, but not comedones.

U.S. Pat. No. 4,725,609 teaches the topical application of nicotinamide to promote angiogenesis, recpithelialization and wound healing.

U.S. Pat. No. 5,459,153 teaches a method for treatment of acne vulgaris comprising administration to a patient of a mixture of pantothenic acid, nicotinic acid, and biotin, to generate nicotinamide in vivo.

U.S. Pat. No. 5,989,523 teaches a topical spray of 1–10% niacinamide with a humectant to treat acne.

U.S. Pat. No. 6,020,351 teaches selectively administering a daily dosage of carotenoids, nicotinamide, and a source of zinc, in excess of normal dietary levels for improving resistance to DNA damage, enhancing DNA repair capacity, and stimulating immune function.

U.S. Pat. No. 6,248,763 teaches the topical application of nicotinamide to treat acne.

It has been reported in the medical literature that acne is often associated with low zinc levels in blood serum and in the epidermal layer. The therapeutic effect of zinc as an anti-inflammatory agent has been well documented, and oral zinc has been reported to be helpful in the treatment of certain types of acne. It is also known that zinc supplementation should be used with copper supplementation to avoid a copper deficiency that might otherwise occur.

SUMMARY OF THE INVENTION

The present invention provides an improved method and composition for the treatment of acne vulgaris, acne rosacea, bullous pemphigoid and other inflammatory skin conditions. The invention relates to the oral administration of a composition comprising a large dose of nicotinamide delivered at levels very substantially in excess of normal dietary levels, the nicotinamide being delivered in immediate release form in combination with a dose of zinc provided in a sustained release form. This combination of immediate release nicotinamide and sustained release zinc provides a level of anti-inflammatory activity substantially exceeding that provided by combinations of immediate release forms of nicotinamide and zinc. The sustained release form of zinc also permits the unopposed absorption of orally administered tetracycline and its cogeners, which are frequently utilized as a part of the treatment regimens for acne vulgaris, acne rosacea and certain other inflammatory cutaneous disorders. In one preferred embodiment of the invention, a quantity of copper is included to avoid the copper deficiency that might otherwise occur due to the zinc supplementation. The composition may also include a quantity of folic acid, which is an essential nutrient in teenagers and women of child-bearing age.

In a most preferred embodiment, nicotinamide and copper and folic acid each are present in immediate release forms, while the zinc is present in a sustained release form. This reduces the interaction between zinc and copper that can reduce the absorption of both. It also reduces the side effects such as nausea that might otherwise be associated with high levels of orally administered zinc

DETAILED DESCRIPTION OF THE INVENTION

The oral composition of the present invention comprises an amount of an immediate release form of nicotinamide very substantially greater than that obtained through the normal diet, combined with a sustained release form of zinc, both delivered in sufficient quantities to provide a therapeutic effect over an extended period for acne vulgaris, acne rosacea, bullous pemphigoid or other inflammatory skin conditions. For purpose of this patent, an immediate release form is one that releases 75% of the active ingredient within two hours of ingestion. A high dose of immediate release nicotinamide increases the bioavailablity of nicotinamide and extends the activity of nicotinamide over that of a sustained release formulation. This unexpected event is unique to oral nicotinamide. The nicotinamide will be present in an amount of at least 250 mg per dose, more

preferably at least about 500 mg per dose, and most preferably at least about 750 mg per dose.

In compositions of the present invention, the sustained release form of zinc will be present in an amount sufficient to provide an anti-inflammatory effect. The zinc may be present in any pharmaceutically acceptable zinc salt, zinc complex or zinc chelate for oral administration. Zinc oxide is one such preferred zinc salt. However, other zinc salts such as zinc sulfate and zinc gluconate, zinc complexes or zinc chelates may be substituted, in the sustained release form for the zinc oxide. Zinc oxide can be present in an amount of about at least about 15 mg per dose, more preferably at least about 20 mg per dose, and most preferably at least about 25 mg per doseCompositions within the scope of the present invention may also include a copper-containing compound. Such a copper-containing compound can be any copper compound or copper salt known to be suitable for oral ingestion for copper supplementation, such as cupric oxide or copper salts including cupric sulfate, as well as copper complexes or chelates, but is preferably in an immediate release format. The copper-containing compound should be present in an amount sufficient to compensate for any copper deficiency that might otherwise occur due to the increased levels of zinc. The copper can be present in an amount of about at least 1.0 milligrams per dose, and more preferably in an amount of about at least 1.5 milligrams per dose, regardless of the form of the copper compound used.

The compositions of the present invention may also include a quantity of folic acid. Folic acid is an essential nutrient for a developing fetus. The diets of many teens and young adults are deficient in folic acid. It is expected that the subject invention will be used primarily by teens and young adults who suffer from acne vulgaris. The use of folic acid in compositions of the present invention is intended to supplement this essential nutrient in this segment of the population. The folic acid can be present in the amount of about at least 500 micrograms.

EXAMPLE 1

A composition is prepared in tablet form, each tablet comprising 750 milligrams immediate release nicotinamide, 25 milligrams sustained release zinc oxide, and 500 micrograms immediate release folic acid. When administered orally twice daily, the tablets are found to be a highly effective treatment for acne vulgaris.

EXAMPLE 2

A composition is prepared in tablet form each tablet comprising 750 milligrams immediate release nicotinamide, 25 milligrams sustained release zinc oxide, 500 micrograms immediate release folic acid, and 1.5 milligrams immediate release copper sulfate. When administered orally twice daily, the tablets are found to be a highly effective treatment for acne vulgaris.

EXAMPLE 3

A composition is prepared in tablet form each tablet comprising 1000 milligrams immediate release nicotinamide, 15 milligrams sustained release zinc oxide, 500 micrograms immediate release folic acid, and 1.0 milligrams immediate release copper sulfate. When administered orally twice daily, the tablets are found to be a highly effective treatment for acne vulgaris.

EXAMPLE 4

A composition is prepared in tablet form each tablet comprising 500 milligrams immediate release nicotinamide, 30 milligrams sustained release zinc oxide, 500 micrograms immediate release folic acid, and 1.5 milligrams immediate release copper sulfate. When administered orally twice daily, the tablets are found to be a highly effective treatment for acne vulgaris.

EXAMPLE 5

A composition is prepared in tablet form each tablet comprising 650 milligrams immediate release nicotinamide, 30 milligrams sustained release zinc oxide, 500 micrograms immediate release folic acid, and 1.5 milligrams immediate release copper sulfate. When administered orally twice daily, the tablets are found to be a highly effective treatment for acne vulgaris.

It is to be understood that the invention is not limited to the features and embodiments hereinabove set forth, but may be carried out in other ways without departing from its spirit.

What is claimed is:

1. An oral pharmaceutical preparation in dosage unit form adapted for administration for the treatment of inflammatory skin disorders, comprising, per dosage unit, at least 250 mg of nicotinamide in an immediate release form, and an amount of zinc in a sustained release form, said amount of zinc being sufficient to provide an enhanced anti-inflammatory effect, in a vehicle pharmaceutically acceptable for oral administration.

2. The oral pharmaceutical preparation of claim **1** wherein said zinc is present as zinc oxide, zinc sulfate, zinc gluconate, zinc complexes or zinc chelates.

3. The oral pharmaceutical preparation of claim **2** wherein said zinc is present as zinc oxide in the amount of about at least 15 mg per dosage unit.

4. The oral pharmaceutical preparation of claim **3** wherein said zinc oxide is present in the amount of about at least 20 mg per dosage unit.

5. The oral pharmaceutical preparation of claim **4** wherein said zinc oxide is present in the amount of about at least 25 mg per dosage unit.

6. The oral pharmaceutical preparation of claim **1** further comprising an amount of folic acid.

7. The oral pharmaceutical preparation of claim **6** wherein said folic acid is present in the amount of at least about 500 micrograms per dosage unit.

8. The oral pharmaceutical preparation of claim **1** wherein said nicotinamide is present in the amount of about at least 500 mg per dosage unit.

9. The oral pharmaceutical preparation of claim **1** wherein said nicotinamide is present in the amount of about at least 750 mg per dosage unit.

10. The oral pharmaceutical preparation of claim **1** further comprising an amount of a copper-containing compound.

11. The oral pharmaceutical preparation of claim **10** wherein said copper-containing compound is in an immediate release form.

12. The oral pharmaceutical preparation of claim **10** wherein said copper-containing compound is selected from the group consisting of cupric oxide, cupric sulfate, copper complexes and copper chelates.

13. The oral pharmaceutical preparation of claim **10** wherein said copper-containing compound is present in an amount of about at least 1.0 milligrams per dosage unit.

14. The oral pharmaceutical preparation of claim 13 wherein said copper-containing compound is present in an amount of about at least 1.5 milligrams per dosage unit.

15. The oral pharmaceutical preparation of claim 1 wherein each dosage unit is in the form of a tablet, capsule or softgel.

16. A method for the treatment of inflammatory skin conditions, the method comprising the step of orally administering to a person having said inflammatory skin condition the oral pharmaceutical preparation of claim 1.

* * * * *

Exhibit B

Intellectual Property Technology Law

Offices: 1414 Raleigh Road
Suite 201, Chapel Hill, NC 27517
USA

Mail: P.O. Box 14329,
Research Triangle Park, NC 27709
USA

Voice: (919) 419-9350
Fax: (919) 419-9354 • (919) 401-1807
E-mail: info@ipti.com
Web: www.ipti.com

March 17, 2006

DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, MA 01887
Attn: Dr. D. Geoffrey Shulman, Chairman and CEO

VIA E-MAIL: gshulman@dusapharma.com
AND FACSIMILE: (978) 657-9193

Sirius Laboratories, Inc.
100 Fairway Drive, Suite 130
Vernon Hills, IL 60061
Attn: Mr. Frank Pollard

VIA E-MAIL: fpollard@siriuslabs.com
AND FACSIMILE: (847) 968-2484

Gentlemen:

We represent a pharmaceutical company that has requested our review of your company's U.S. Patent No. 6,979,468 relating to an oral formation of nicotinamide and zinc (the '468 patent).

In the course of our review, we located a substantial amount of prior art that shows the claims issued in the '468 patent to be invalid. This prior art includes, for example (since we identify here only some of the many references relating to oral formulations of nicotinamide and zinc), U.S. Patent No. 5,053,396; U.S. Patent No. 4,237,118; U.S. Patent No. 5,962,517; U.S. Patent No. 5,804,594; and U.S. Patent No. 6,558,656.

We therefore require that Sirius/DUSA take cognizance of the applicable state of the art, and file in the U.S. Patent and Trademark Office a dedication to the public and disclaimer of the entire remaining term of such patent, under the provisions of 35 USC 253, by March 24, 2006.

Be governed accordingly.

Sincerely,

INTELLECTUAL PROPERTY/TECHNOLOGY LAW

Steven J. Hultquist
Principal

Sirius/DUSA ltr01

Exhibit C

Vinson&Elkins

Tracey Davies tdavies@velaw.com
Tel 512.542.8619 Fax 512.236.3267

March 23, 2006

Mr. Steven J. Hultquist
Intellectual Property Technology Law
1414 Raleigh Road, Suite 201
Chapel Hill, NC 27517

Re: *U.S. Patent No. 6,979,468*

Dear Mr. Hultquist:

We represent DUSA Pharmaceuticals, Inc. ("DUSA"), which recently acquired Sirius Laboratories, Inc. and are in receipt of your letter to them dated March 17, 2006. We have reviewed the five U.S. patents identified in your letter, and have concluded that these patents do not, either alone or in any combination, establish a reasonable basis for questioning the validity of U.S. Patent No. 6,979,468 (the '468 patent). Furthermore, any invalidity opinion based upon the disclosures of these patents would have no objective basis, and thus could not reasonably be relied upon by any client as justification for operating within the scope of the '468 patent claims. If you disagree, please provide us with a detailed claim chart, indicating how these references apply to any claims which you contend are not valid.

Additionally, your letter indicates that you are in possession of other references which you believe to be relevant to the validity of the '468 patent. If these additional unspecified references contain disclosures similar to those you have provided, they will likewise fail to form the basis, alone or in combination, for invalidity of the '468 patent. If, however, you believe you have identified any relevant or material prior art to the '468 patent, please do send it along to us for consideration, and point out the relevance or materiality, if any, to the claims.

Finally, in light of your client's apparent concern that they are or plan to be engaged in activities which may be encompassed by the claims of the '468 patent, we find it curious that your client does not wish to identify itself and approach DUSA to discuss their activities, or intended activities, and a potential business resolution. DUSA would greatly appreciate

the opportunity to engage in such discussions with your client, and requests that they identify themselves to DUSA and initiate such discussions.

Best regards,

Tracey Davies

Exhibit D

AO 440 (Rev. 10/93) Summons in a Civil Action

United States District Court

NORTHERN DISTRICT OF GEORGIA, GAINESVILLE DIVISION

River's Edge Pharmaceuticals, LLC

V.

DUSA Pharmaceuticals, Inc. and
Sirius Laboratories, Inc.

SUMMONS IN A CIVIL CASE

CASE NUMBER:

2 06-CV-0045-WCO

TO: (Name and address of defendant)

Sirius Laboratories, Inc.
c/o CT Corporation System, Registered Agent
208 So LaSalle St, Suite 814
Chicago, IL 60604-1101

DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, MA 01887
ATTN: Peter Chakoutis, Registered Agent

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Robert G. Brazier
Joshua Tropper
Gambrell & Stolz, LLP
3414 Peachtree Road, NE, Suite 1600
Atlanta, GA 30326
404-577-6000
404-221-6501 - facsimile

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

LUTHER D. THOMAS

CLERK

(BY) DEPUTY CLERK

3/28/06

DATE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

RIVER'S EDGE PHARMACEUTICALS, LLC,

Plaintiff,

v.

DUSA PHARMACEUTICALS, Inc., and SIRIUS LABORATORIES, Inc.,

Defendants.

Case No. 2 06-CV-0045 -WCO

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff RIVER'S EDGE PHARMACEUTICALS, LLC, avers:

THE PARTIES

1. Plaintiff is a limited liability company organized and existing pursuant to the laws of the State of Georgia, with its principal place of business at 5400 Laurel Springs Parkway, Building 504, Suwanee, Georgia. Plaintiff markets a prescription-only pharmaceutical product called "NIC 750," indicated for non-pregnant patients with acne vulgaris, acne rosacea or other inflammatory skin disorders who are deficient in, or at risk of deficiency in, one or more of the components of NIC 750.

2. Plaintiff is informed and believes, and on that basis avers, that

Defendant DUSA Pharmaceuticals, Inc., is a corporation organized pursuant to the laws of the State of New Jersey, with its principal place of business at 25 Upton Drive, Wilmington, Massachusetts. DUSA is primarily engaged in the business of pharmaceutical research, development and marketing. Plaintiff is informed and believes, and on that basis avers, that DUSA markets its products in this District.

3. Plaintiff is informed and believes, and on that basis avers, that Defendant Sirius Laboratories, Inc. ("SIRIUS") is a corporation organized pursuant to the laws of the State of Illinois, with its principal place of business at 100 North Fairway Drive, Suite 130, Vernon Hills, Illinois. SIRIUS is engaged in the development and marketing of prescription and nonprescription products for the treatment of skin disorders, including a prescription-only pharmaceutical product under the brand name "NICOMIDE," indicated for non-pregnant patients with acne vulgaris, acne rosacea or other inflammatory skin disorders who are deficient in, or at risk of deficiency in, one or more of the components of NICOMIDE. Plaintiff is informed and believes, and on that basis avers, that SIRIUS markets NICOMIDE in this District. SIRIUS is a wholly-owned subsidiary of DUSA.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. §§ 1331, 1332(a)(1) and 1367(a).

5. Venue in this District is pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(a).

6. Venue in this Division is pursuant to LR 3.1(B)(3), NDGa.

FIRST CLAIM FOR RELIEF:
PROMISSORY ESTOPPEL AGAINST BOTH DEFENDANTS

7. Plaintiff repeats the averments of ¶¶ 1-6 and incorporates them here by this reference as if set forth here in full.

8. SIRIUS has marketed a prescription-only pharmaceutical product under the brand name "NICOMIDE," indicated for treatment of certain inflammatory skin disorders such as acne vulgaris and acne rosacea, since 2001.

9. Beginning in the summer of 2003, Plaintiff and SIRIUS agreed that SIRIUS would authorize Plaintiff to market a low-cost product containing the same active ingredients as NICOMIDE, on a profit-sharing basis. Plaintiff is informed and believes, and on that basis avers, that Plaintiff's share of the profits that would have been generated by that agreement, if SIRIUS had honored it, would have been approximately $2.25 million dollars per year, beginning in mid-2003.

10. SIRIUS repeatedly agreed to reduce the agreement to writing, but failed to do so.

11. Plaintiff reasonably relied on SIRIUS's agreement to authorize Plaintiff to market a low-cost product containing the same active ingredients as NICOMIDE in deferring entering into the market, and in concentrating its product development efforts on other products for which it did not have the benefit of such an agreement, while awaiting execution of the written agreement that SIRIUS had promised.

12. Throughout their discussions, SIRIUS concealed from Plaintiff the material fact that SIRIUS had filed a patent application relating to its NICOMIDE product in December 2002. Plaintiff is informed and believes, and on that basis avers, that SIRIUS's conduct was intended to induce Plaintiff not to enter the market with a competing product before SIRIUS's patent application was granted.

13. On December 27, 2005, U.S. Patent No. 6,979,468, for "Oral composition and method for the treatment of inflammatory cutaneous disorders" ("the '468 Patent") was issued to SIRIUS. In reliance on the '468 Patent, SIRIUS has taken the position that it has no obligation to honor its agreement with Plaintiff and that any product containing the same active ingredients as its NICOMIDE product would infringe the '468 patent.

14. On or about March 13, 2006, DUSA acquired all the outstanding capital stock of SIRIUS. Plaintiff is informed and believes, and on that basis avers, that DUSA is liable for the acts and omissions of SIRIUS.

15. On or about March 21, 2006, pursuant to the merger agreement between SIRIUS and DUSA, DUSA recorded an assignment of SIRIUS's rights to the '468 Patent with the United States Patent & Trademark Office.

WHEREFORE, Plaintiff prays for (a) damages in an amount to be determined at trial; and (b) a declaration of Plaintiff's rights to make, have made and sell its NIC 750 product notwithstanding the '468 Patent.

SECOND CLAIM FOR RELIEF
FRAUD AGAINST BOTH DEFENDANTS

16. Plaintiff repeats the averments of ¶¶ 1-15 and incorporates them here by this reference as if set forth here in full.

17. Plaintiff is informed and believes, and on that basis avers, that Plaintiff's profits from the sale of a competing product, if SIRIUS had acted in good faith and timely notified Plaintiff that it had no intention of honoring any agreement with Plaintiff, would have been approximately five million dollars per year, beginning in late 2003.

WHEREFORE, Plaintiff prays for damages in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF:
DECLARATION OF PATENT INVALIDITY
AGAINST BOTH DEFENDANTS

18. Plaintiff repeats the averments of ¶¶ 1-17 and incorporates them here by this reference as if set forth here in full.

19. Plaintiff is informed and believes, and on that basis avers, that the '468 Patent is invalid over prior art.

20. On or about March 20, 2006, counsel for Plaintiff notified both Defendants in writing of the prior art rendering the '468 Patent invalid, and requested that Defendants dedicate to the public and disclaim the remaining term of the '468 Patent pursuant to 35 U.S.C. § 253, by March 24, 2006. A copy of Plaintiff's notice is attached as Exhibit 1.

21. Defendants have failed and refused to comply with Plaintiff's request.

22. On March 23, 2006, counsel for DUSA responded in writing, denying that the prior art cited by Plaintiff in Exhibit 1 established a basis for invalidating the '468 Patent. A copy of DUSA's response is attached as Exhibit 2.

23. As a result, a real and present controversy exists between the parties as to the validity of the '468 Patent. In light of SIRIUS's deceitful prior conduct,

the implication in Exhibit 2 that DUSA might be seriously interested in "a potential business resolution" of the controversy is not credible and appears to have been intended to induce Plaintiff to further delay its entry into the market.

24. On or about March 27, 2006, Plaintiff began marketing its NIC 750 product in competition with Defendants' NICOMIDE product.

25. Plaintiff is reasonably apprehensive that Defendants will sue Plaintiff for patent infringement, notwithstanding the invalidity of the '468 Patent, to avoid lawful competition.

WHEREFORE, Plaintiff prays for a declaration of the invalidity of the '468 Patent.

DATED: March 28, 2006

GAMBRELL & STOLZ, L.L.P.

By: _____

Robert G. Brazier
Georgia Bar No. 078938
Joshua Tropper
Georgia Bar No. 716790
Suite 1600, Monarch Plaza
3414 Peachtree Road, N.E.
Atlanta, Georgia 30326

404-577-6000 (Telephone)
404-221-6501 (Facsimile)
Attorneys for Plaintiff

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury of every issue in this action triable of right by a jury.

DATED: March 28, 2006

GAMBRELL & STOLZ, L.L.P.

By: _____

Robert G. Brazier
Georgia Bar No. 078938
Joshua Tropper
Georgia Bar No. 716790
Suite 1600, Monarch Plaza
3414 Peachtree Road, N.E.
Atlanta, Georgia 30326

404-577-6000 (Telephone)
404-221-6501 (Facsimile)
Attorneys for Plaintiff

VERIFICATION

On behalf of Plaintiffs DUSA Pharmaceuticals, Inc. and Sirius Laboratories, Inc., I, Scott Lundahl, being of full age, hereby declare as follows:

1. I am employed by Plaintiffs as their Vice President, Regulatory Affairs and Intellectual Property. As such I have been duly authorized to submit this Verification.
2. I have read the foregoing Verified Complaint and have personal knowledge of the facts surrounding this controversy. I verify and declare that, based upon all of the information presently available and known to me, all of the allegations contained in the foregoing Verified Complaint are true to the best of my information, knowledge and belief.

I further verify and declare that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Scott Lundahl

Scott Lundahl By permission by MJSM

DATED: 4-20-06

DECLARATION OF COUNSEL

I, Michael J. Smith, an attorney at law duly licensed to practice in the State of Texas and counsel for Plaintiffs in this matter, declare that Mr. Scott Lundahl granted me permission to sign the Verification for this complaint on his behalf as he was unavailable to sign. Plaintiffs will file a substitute Verification signed by Mr. Lundahl in due course if so requested by the Court.

Michael J. Smith

DATED: 4-20-06